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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,212	06/07/2002	Atsushi Miyamoto	Q68293	4780

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EXAMINER	
COOK, LISA V	

ART UNIT	PAPER NUMBER
1641	

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08/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/048,212	MIYAMOTO ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-6,9 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-6,9 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicants response to the Office Action mailed January 4, 2007 is acknowledged. In the amendment filed therein, claims numbered 1 and 6 were modified. Claims 2, 3, 7, and 8 were canceled without prejudice or disclaimer. Currently, claims 1, 4-6, and 9-10 are pending and under consideration.

2. Objections and/or rejection of record not reiterated herein have been withdrawn.

NEW GROUNDS OF REJECTION NECESSIATED BY AMENDMENT

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claims 1 and 6 the language "consisting essentially of *about*" is vague and indefinite because the fragment content it is not clear. Will the fragment consist essentially of 2-10? As recited it's not clear what will be considered about 2-10 fragments? The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. As recited the metes and bounds of the claim cannot be determined. It is suggested that the claim merely recite "consisting essentially of 2-10 fragments in order to obviate this rejection.

REJECTIONS MAINTAINED

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 1, 4, 6, and 9 are rejected under 35 U.S.C.103(a) as being unpatentable over Hunter et al. (Int. Arch. Allergy, 36 354-375, 1969) in view of Dosa et al. (Immunology, 1979, 38, pages 509-517) and further in view of Scherr (US Patent #4,096,138).

Hunter et al. teach agglutination procedures to measure antibody-antigen binding. In one embodiment, pepsin treated antibodies are coupled to BSA (protease treated BSA) and use to measure antigen interaction via agglutination. See pepsin of F(ab)2 fragments and 7S on page 356; page 363. Bovine serum albumin (BSA) is proven useful in being coupled to reagents while the reagent binding ability in agglutination procedures is maintained. See page 361 number 2 and table IV.

Hunter et al. are silent with respect to the pepsin digest rendering fragmented BSA. However, Dosa et al. disclose the effect of peptic degradation on the immunological and antigenic properties of bovine serum albumin (BSA). See abstract. BSA was digested with pepsin and the fluorescence-binding efficiency evaluated. The BSA fragments obtained from a digest did not form BSA-anti-BSA immune complexes (see page 511-512) and did not interact with B cells (see page 516, 1st column 1st paragraph). The systematic degradation of BSA with pepsin provided an excellent model for investigating the function and nature of different antigenic determinants present on protein antigens. Page 515, 2nd column – Discussion.

Hunter et al. discloses the claimed invention except for the fragmented BSA produced from pepsin digestion.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to degrade BSA with pepsin thereby producing fragmented BSA because Dosa et al. taught that the systematic degradation of BSA with pepsin provided an excellent model for investigating the function and nature of different antigenic determinants present on protein antigens. Page 515, 2nd column – Discussion.

Hunter et al. in view of Dosa et al. differ from the instant invention in not specifically teaching the utility of BSA coated latex particles carrying an antibody or antigen specifically reactive with the analyte of interest.

Scherr teach this limitation. Specifically, Scherr disclose immunological test procedures. The agglutination tests involving proteins coupled to particles. See column 1 lines 24-43. The use of BSA coated surfaces is taught to eliminate spatial interference due to steric hindrance. See column 2 lines 38-68.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to use a BSA coated latex assay as taught by Sherr with the BSA protease pre-treatment method of Hunter et al. in view of Dosa et al. because Sherr taught The use of BSA coated surfaces is taught to eliminate spatial interference due to steric hindrance. See column 2 lines 38-68.

One of ordinary skill in the art would have been motivated to use BSA coated latex in order to reduce interferences.

Response to Arguments

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that the rejection is overcome and/or traversed at least because Dosa et al. does not teach that fragmented BSA consisting of about 2 to 10 fragments is capable of preventing a non-specific reaction. This argument was carefully considered but not found persuasive because the features upon which applicant relies (i.e., capable of preventing a non-specific reaction) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In addition, it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

(1) Protease-treated fragmented BSA used in the present invention

Applicant contends that the specification discloses that fragmented BSA was prepared by digesting BSA with pepsin at a ratio of 0.167mg:500mg(=1:3000, pepsin:BSA) at 25°C for 30 minutes in Example 1. This argument has been carefully considered but not found persuasive because these specific features are not recited in the rejected claim(s). The claims merely read on pepsin fragmentation of BSA to produce about 2 to 10 fragments. As contended by Applicant (see page 8 -last paragraph of the response filed 6/4/07), Dosa et al. teach conditions at 6 minutes with pepsin BSA is cleaved into 10 to 11 fragments (which reads on the instant claims of about 2 to 10 fragments). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

(2) BSA fragments digested with pepsin disclosed in Dosa et al.

Applicant contends that the effect of BSA fragments disclosed in Dosa et al. is known as "immunological tolerance" in a living body and does not teach or suggest the prevention of a non-specific reaction of latex particles in an immunological turbidimetry method. This argument was carefully considered but not found persuasive because an obviousness rejection is proper so long as the prior art suggests a reason or provides motivation to make the claimed invention, even where the reason or motivation is different from that discovered by applicant. *In re Dillon*, 919 F.2d 688, 696, 16 USPQ 2d 1897, 1904, (Fed. Cir. 1990) (in banc), cert.denied, 111 S.Ct. 1682, (1991).

In addition, Dosa et al. is cited in combination with Hunter et al. and Scherr to make obvious the use of "protease (pepsin) treated fragmented bovine serum albumin" in latex particle agglutination procedures. *A priori,* it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to use a BSA coated latex assay as taught by Sherr with the BSA protease pre-treatment method of Hunter et al. in view of Dosa et al. because Sherr taught The use of BSA coated surfaces is taught to eliminate spatial interference due to steric hindrance. See column 2 lines 38-68. One of ordinary skill in the art would have been motivated to use BSA coated latex in order to reduce interferences.

Applicant contends that Dosa et al. do not teach fragmented BSA consisting essentially of about 2 to 10 fragments. This argument was carefully considered but not found persuasive because Dosa et al. utilize the same fragmenting agent (pepsin) as the specification (Example1). The use of pepsin at a concentration that produces about 2 to 10 fragments of BSA would have been obvious to one having ordinary skill in the art at the time the invention, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Applicant argues that in order to achieve the recited fragmented BSA consisting essentially of about 2 to 10 fragments, the instant disclosure employs a 1:3000 pepsin:BSA ratio for 30min (page 7, (1) of the response filed 6/4/07). This argument was carefully considered but not found persuasive because the method to Dosa et al. utilizes a 1:650 pepsin:BSA ratio from 3-360min (See page 510, 1st column, 2nd paragraph). Thus it would appear that the concentration of Dosa et al. would achieve the recited fragmentation parameters currently recited.

Applicant further contends that Dosa et al. teach BSA cleavage into 10 to 11 fragments, but the fragments do not exhibit immunological suppression effects in the living body. This argument was carefully considered but not found persuasive because the features upon which applicant relies (i.e., immunological suppression effects in the living body) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant contends that Dosa et al. teaches away from using protease-treated fragmented BSA consisting essentially of about 2 to 10 fragments, because Dosa et al. teaches that the BSA fragments do not have immunological suppression effects in the living body. Thus, one of ordinary skill in the art would not be motivated by Dosa et al. to use protease-treated fragmented BSA in latex turbidimetry method. This argument was carefully considered but not found persuasive because Hunter et al. teach agglutination procedures to measure antibody-antigen binding. In one embodiment, pepsin treated antibodies are coupled to BSA (protease treated BSA) and use to measure antigen interaction via agglutination. See pepsin of F(ab)2 fragments and 7S on page 356; page 363. Dosa et al. were merely cited to show that pepsin will fragment BSA (a compound and its properties are inseparable. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)). Furthermore, "[t]he prior art's mere disclosure of more than one alternative (*in vivo* utility) does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed...." In re Fulton, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004).

Although, Dosa et al. teach in vivo procedures for immunological tolerance it does not criticize, discredit, or discourage the pepsin/BSA agglutination procedures set forth by Hunter et al. The test for obviousness is not whether the features of one reference may be bodily incorporated into the other to produce the claimed subject matter but simply what the combination of references makes obvious to one of ordinary skill in the pertinent art. See *In re Bent*, 52 CCPA 850, 144 USPQ 28 (1964); *In re Nievelt*, 179 USPQ 224 (CCPA 1973).

II. Claims 5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter et al. (Int. Arch. Allergy, 36 354-375, 1969) in view of Dosa et al. (Immunology, 1979, 38, pages 509-517) and further in view of Scherr (US Patent #4,096,138) as applied to claims 1, 4, 6, and 9 above, and further in view of Nakase et al. (JP 48019719 Abstract Only).

Please see Hunter et al. in view of Dosa et al. and further in view of Scherr as set forth above. Hunter et al. in view of Dosa et al. and further in view of Scherr. disclose the reagent combination involving protease treatment in combination with BSA and antigen/antibody coated BSA latex particles. However, Hunter et al. in view of Dosa et al. and further in view of Scherr do not teach the use of these reagents for anti-streptolysin O antibodies.

Nakase et al. disclose that the addition of BSA (bovine serum albumin) to streptolysin O stabilizes streptolysin O and allows streptolysin O to maintain its activity. See abstract.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the protease treatment in combination with BSA and antigen/antibody coated latex particles detection reagents as taught by Hunter et al. in view of Dosa et al. and further in view of Scherr and utilize them in turbidity measurements for anti-streptolysin O antibodies/antigen assays because Nakase et al. disclose that the addition of BSA (bovine serum albumin) to streptolysin O stabilizes streptolysin O and allow streptolysin O to maintain its activity. See abstract.

Response to Arguments

Applicants contend that the rejection is traversed and/or overcome because Nakase et al. does not supply the deficiencies in Dosa et al. This argument was carefully considered but not found persuasive because Dosa et al. is maintained. The arguments against Dosa et al. are addressed above. For the reasons noted herein, the rejections are maintained.

5. For reasons aforementioned, no claims are allowed.

Remarks

6. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Masson et al. (EPO 0 061 857 A1) disclose pepsin digestion to eliminate protein interferences. See page 8 lines 25 through 30.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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